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PATENT

19318/109

1615

In re Application of:

Bosch et al.

Serial No.: 09/190,138

Filed: November 12, 1998

Group Art Unit: 1615

Examiner: P.E. McQueeney

For: DRY POWDER AEROSOLS OF NANOPARTICULATE DRUGS

Commissioner for Patents
Washington, D.C. 20231
BOX AF

Sir:

AMENDMENT UNDER 37 C.F.R. § 1.116

This Amendment is filed in response to the Office Action mailed on February 5, 2001, a shortened statutory response to which is due by May 5, 2001.

IN THE CLAIMS:

11. An aerosol composition comprising:

(a) aggregates of a spray-dried powder comprising nanoparticulate drug particles, wherein the nanoparticulate drug particles:

- (i) comprise a poorly soluble crystalline drug, wherein by "poorly soluble" it is meant that the drug has a solubility in at least one liquid dispersion medium of less than about 10 mg/ml,
- (ii) have an effective average particle size of less than about 1000 nm, meaning at least 50% of the drug particles have a particle size of less than about 1000 nm, and
- (iii) have a surface modifier adsorbed on the surface thereof; and

(b) the aggregates of spray-dried drug particles are less than or equal to about 100 microns in diameter,

wherein the dry powder aggregates are formulated into an aerosol composition.